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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,316	04/02/2004	Xinghui He	TTC-005XX	1106
207 7590 09/27/2010 WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER CWERN, JONATHAN				
ART UNIT		PAPER NUMBER		
3737				
MAIL DATE		DELIVERY MODE		
09/27/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/817,316

Applicant(s)

HE ET AL.

Examiner

Jonathan G. Cwern

Art Unit

3737

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 28-34 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 and 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 28-34 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/10 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18, 28-34, and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (US 6450959) in view of Criton et al. (US 5800356), Rubin et al. (US 2003/0195413), and Schechter (US 2005/0043895).

Mo et al. show methods and apparatus for simultaneous B-mode and multi-gate spectral Doppler imaging by an ultrasound scanner system (column 2, lines 50-55). Two or more independent Doppler beams are generated by the transmitter array to sample different vessel locations, each beam being multi-gated (column 4, lines 60-65). Figure 7 shows the two spectral lines in the same image frame. The spectral data is superimposed onto the B-image (tissue Doppler image, column 4, lines 45-55). Also, an ECG signal can be used as a trigger signal (column 5, lines 25-26). Mo et al. also mention that this device would be useful for monitoring flow profile changes in conjunction with vessel wall movements over the cardiac cycle (column 1, lines 58-63). Mo et al. also use a wall filter, which is a type of high pass filter (column 3, lines 60-65) and show a pre-set velocity scale (Figure 3, velocity axis) as is typical in a spectral Doppler display. Regarding claim 18, it is well known and expedient to use standard operating guidelines to perform echocardiography imaging operations. However, Mo does not go into specific details of tissue motion, and does not specifically mention applying the gates to a heart wall. Mo also fails to show measuring strain and using the measurements to select settings for a pacemaker.

Criton et al. disclose an ultrasonic diagnostic imaging system with Doppler assisted tracking of tissue motion. Criton et al. teach identifying the borders of the heart

wall (column 1, lines 55-65); using automatic border detection, identifying a boundary (anchor) point (column 3, lines 5-20); identifying a boundary (anchor) point; measuring and displaying the displacement of the walls (column 6, line 64-column 7, line 15); obtaining and displaying velocity data (column 6, lines 5-15); identifying and displaying the direction of motion (column 6, lines 5-15); obtaining information over a time interval (column 3, lines 25-27); proving apical images with at least two chambers (Figure 2), and short axis view of the heart (Figure 10).

Rubin et al. disclose a method for generating a gating signal for an MRI system using an ultrasonic detector. Rubin et al. teach that a gate can be applied to a heart wall ([0046] and [0059]).

Schechter discloses a method and apparatus for automatically programming CRT devices. Schechter teaches using ultrasound to measure strain and heart motion to use as quantitative parameters to indicate ventricular dysynchrony. The motion of the heart is directly related to the phase of the cardiac cycle, and thus the phase of the heart is used to aid in determining dysynchrony. The regions measured by the ultrasound can be lateral and septal walls. These walls are desirable to measure as they can show the most significant dysynchrony ([0069]-[0072]). It would be obvious to one of ordinary skill in the art, as an obvious design choice, to measure any walls of the heart which would yield a useful result. The data obtained is used to program a CRT device for biventricular pacing ([0055]). The thickness of the walls can also be measured ([0075]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used B-mode imaging and Doppler information to identify motion of the heart. Mo et al. briefly mention that their invention can be used to study vessel wall movements over the cardiac cycle (column 1, lines 58-63), but do not go into the specific details of calculating the tissue motion. Criton et al. provide a system and method to calculate and display tissue motion of the heart, and describe calculating and displaying the tissue motion in detail. One of ordinary skill in the art could have used the system of Mo et al. to calculate tissue motion of the heart taught by Criton et al. It would be obvious to have applied the gate to a heart wall as taught by Rubin et al., when the object of interest is the heart. It would be obvious to apply gates to any structure in the body which is being observed. Further, it would be obvious to use such an invention for any particular application which requires ultrasonic measurements of the heart. For example, the invention could be used for measuring indicators of ventricular dysynchrony, such as motion, to select settings for a pacemaker as taught by Schechter.

Response to Arguments

Applicant's arguments filed 9/10/10 have been fully considered but they are not persuasive.

In regards to applicant's arguments that one of ordinary skill in the art would not apply the fluid measurement techniques of Mo et al. for measuring tissue movement, examiner respectfully disagrees. It is known in the art to apply range gates to a number

of different structures in the body, depending on the body part being studied.

Specifically, in regards to cardiac gating, it is known to apply gates to either observe heart wall motion or blood flow. Furthermore, it is known to apply gates directly on the heart, or on peripheral blood vessels. These features are all disclosed by Rubin et al. ([0046]-[0048]) and provide further evidence that one of ordinary skill in the art would apply the gating techniques of Mo et al. to study blood flow or wall motion.

In regards to applicant's arguments that Criton et al. do not teach using two gated Doppler lines to measure separate wall locations or selecting lead delay settings, it should be noted that the examiner has not relied upon Criton et al. to teach these features.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Mo et al. is relied upon to show the two lines, and as stated above it would be obvious to apply such techniques to study wall motion as well. Mo et al. also shows using both B-mode and Doppler images to form the gates. Furthermore, Schechter notes that using Doppler imaging to quantify wall velocity allows for qualification and quantification of myocardial dysynchrony ([0028]), which can be corrected by using pacemakers ([0024]). This further demonstrates that it is known to use ultrasound to measure dysynchrony for a pacemaker treatment. Schechter provides further

reasoning for measuring two distinct regions of tissue, as analyzing the lateral and septal walls will aid in determining areas with the most significant dysynchrony ([0069]). Thus, it would be obvious to one of ordinary skill in the art to measure these two walls using a technique such as that shown by Mo et al.

It should also be noted in regards to new claims 45 and 46, applicant admits in their own published specification that these features are known in the art (preset velocity scale is "standard", [0074]; high pass filtering known in the arts ([0077]), and thus these features would not patentably distinguish over the prior art. In any case, these features are also shown in the Mo et al. reference.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

